How do I do primary research when I can't interact with people?

Adapting to the impact of COVID-19 on undergraduate and honours student research projects in the FMHS

South Africa is currently in national lockdown. Even after lockdown has been lifted/eased, "non-essential" research that involves face-to-face interaction between and with participants will likely continue to be embargoed by Stellenbosch University (read position statement here) and by the Health Research Ethics Committee (HREC) at our Faculty of Medicine and Health Sciences (read position statement here). The date that this embargo will be/ is lifted will be published on the HREC website when this decision is made.

This means that data collection on many undergraduate and honours student research projects will likely not be able to continue as originally planned. The **purpose of this brief resource document is to give some pointers to students to link to relevant guidance and information, depending on what amendment decisions they and their supervisors may be needing to make regarding their research projects**. (Note: this guidance applies to primary research studies, not secondary research studies such as systematic reviews or scoping reviews etc.).

Remember: Having to respond to these unexpected events and make changes to your carefully laid plans may seem overwhelming, but it is not impossible: you will still be able to complete your research in one form or another, it's just going to involve a few more/different steps and a bit more time than you originally anticipated. That's real research!

General resources: all research must be ethically conducted

- Regardless of whether your research is going ahead as planned or changing, all research needs to be conducted in an ethically sound manner. This video covers the basic principles of ensuring that your research is ethical, and the Department of Health (DoH) ethics guidelines and HREC Standard Operating Procedures (SoPs) give lots of guidance on different ethical considerations.
- Additional guidance on **ethical considerations that are specifically applicable to doing research during global emergencies and public health crises** are given at the end of this document.
- Also remember that **all other relevant permissions** that need to be obtained, depending on your target population, also still apply – e.g. permission from the Division for Information Governance and from relevant programme committees (e.g. MB,ChB programme committee for research involving MB,ChB students) if you are doing research involving SU students or staff, or permission from health facility management if your research involves patients or patient data.

Starting new project / busy with protocol

- This represents a great time to plan your research, make **progress on completing a research protocol,** and/or **submit an ethics application** to the Undergraduate Research Ethics Committee.
- Consider the **need for research on COVID** and its impact on all aspects of life/society, including on your own education/training!
- Visit the Undergraduate Research Office (URO) website and particularly the Roadmap to Research resource for information and guidance no matter where you are in the research process.
- Get input/assistance from URO head, Debbie Marais (debbiem@sun.ac.za) if you are stuck or have no idea where to begin.
- Book an online consultation with the Biostatistics Unit (free for students!) if you need input on your quantitative study design, sample size calculations, and statistical analysis.
- **Factor in possible restrictions on data collection** in the short- and medium-term due to our current uncertain circumstances.

- **Factor in the impact of COVID** – and all the knock-on consequences – on the world, communities, and individuals. This requires sensitive consideration around requesting participation in the first place and engaging in the informed consent process with potential participants.

Changing methodology: making amendments to your existing protocol

- If you are having to change any part of your study design or methodology (including data collection procedures), it is important to **ensure that your research is still scientifically sound and valid**, and that the chosen methodology is still appropriate to the research question, aims, and objectives. If this is not the case, you will need to think about adapting your research question to ensure that scientific validity is still achieved.
- One of the other important considerations in amending your research protocol is making sure that the **methodology you choose will still be feasible within your (probably revised) time frame** (e.g. changes to your class schedule and timing of data collection period).
- Making any amendments to a research protocol that has already received ethics approval will mean that you need to **submit an amendment application to the ethics committee.** This video gives guidance on what is required and how to submit an amendment application online.
- You will need to decide with your supervisor whether your amendments would be considered **minor or major amendments** (the amendment application will ask you to select one of these options). You can find what sorts of changes are considered minor versus major in section 9.2 on pages 44-46 of the HREC SoPs.
- If you had originally planned to collect data from participants in any face-to-face manner (e.g. doing questionnaires, interviews, or focus groups), you will likely be needing to **identify other appropriate methods of collecting data**. Some examples include: * doing retrospective analysis of data that has already been collected, through hospital databases or in other research projects, * adapting your questionnaire so that it can be sent out as an online survey, * changing your interviews from face-to-face to telephonic or online/virtual video calls. Some pointers for each of these kinds of methods are provided below.

Retrospective review of existing data

- When you do research that uses and analyses **data that has already been collected** – whether as part of routine health records (e.g. hospital files or databases) or as part of another research study – you will be using a retrospective record review study design and data collection method.
- In ethics guidance, using this kind of data in research is known as "secondary use" of stored data. There are important **implications for obtaining consent** – **or the waiving of consent** – in order to use this data.
- Find brief guidance on consent requirements when your research involves **secondary use of data or samples here**.
- Find brief guidance on requirements when applying to the ethics committee for a **waiver of consent** here.
- You can also find guidance on this in section 3.3.7 on pages 43-44 of the DoH ethics guidelines and sections 11.5.8 and 11.5.9 on pages 59-60 of the HREC SoPs.

Survey research online

- There are **three main ethical considerations when conducting online survey research:** i) how you legally and ethically obtain potential participants' contact details in order to make contact; ii) the online consent process and documentation thereof; and iii) ensuring the security of the data in order to protect participants' confidentiality.
- In terms of **how you legally and ethically obtain potential participants' contact details in order to make contact,** you need to ensure that you are adhering to the regulations regarding protection of

personal information set out in the **Protection of Personal Information (POPI) Act**. An important thing to bear in mind here is that personal information – including contact details such as email addresses – that was obtained for one purpose (e.g. students enrolling in a class, or patients attending health checks at a clinic) – is not allowed to be shared with third parties (e.g. you, as researchers) without explicit consent from the person who provided their contact details for the original purpose. So, if you intend to email students to request participation in your research and you happen to have access to all classes' email addresses as a result of your role as class rep, it would not be legal for you to use these contact details for the purposes of your research. This is why the tyg@sympa email distribution listservs exist: you can send the email to these general emails and the moderator of these listservs can decide if the communication is appropriate to send to the relevant email distribution list. Staff at our Division for Information Governance would be able to advise on navigating the conditions of the POPI Act: permission@sun.ac.za.

- In your application to the ethics committee, you would need to **submit both the text of the email that you plan to send out with the link to the online survey**, as well as **the online consent form** (page) that potential participants would be directed to when they click on the link, which should be an adapted version of a typical informed consent form. You should **only include all email addresses in the BC (blind copy) field** of the email's TO: line to avoid all potential participants seeing who is being contacted and therefore breaching confidentiality. To be safe, the email should still caution recipients of using the 'reply all' function on emails to avoid breaching their own confidentiality.
- You can find a **template for an online informed consent form** on the HREC Forms and Instructions page.
- You will need to describe in your protocol **how you plan on anonymising or de-identifying the online survey responses** in order to protect participants' confidentiality, as well as the measures you will put in place to **avoid breaches of security and minimise risks to confidentiality** on online platforms, including how and where you will store this data after participants submit the survey.
- If you plan to offer an incentive for participation, you need to outline **how participants can submit their contact details to qualify for the incentive** in a way that completely separates this response from their survey responses (and therefore keeps the latter anonymous).

Telephonic interviews

- If you plan to conduct interviews telephonically, you should **ideally give or send information about the research to potential participants in writing before hand** (e.g. sending the informed consent document to them via email), which they can read and sign to send back to you. If people agree to the telephone interview having read this information, you should nonetheless conduct a verbal consent process when contacting them telephonically, to ensure that participants have read and fully understood the information, and to allow for any questions, before commencing with the interview.
- Where it is not possible to follow this first step (e.g. where potential participants' access to electronic communication and connectivity is limited), the whole consent process may need to occur verbally, over the telephone. **There are three main ethical considerations when contacting people to request their participation in a research study over the telephone**: i) how you legally and ethically obtain potential participants' contact details in order to make contact; ii) the steps you follow in the informed consent process, over the telephone; and iii) how you document both the informed consent process and the consent that participants verbally (telephonically) give.
- In terms of **how you legally and ethically obtain potential participants' contact details in order to make contact,** you need to ensure that you are adhering to the regulations regarding protection of personal information set out in the **Protection of Personal Information (POPI) Act**. An important thing to bear in mind here is that personal information – including contact details – that was obtained for one purpose (e.g. students enrolling in a class, or patients attending health checks at a clinic) – is not allowed to be shared with third parties (e.g. you, as researchers) without explicit consent from the

person who provided their contact details for the original purpose. So, if you intend to contact patients from a health facility, for example, the health facility would first need to contact potential participants to ask for their permission for the facility to give you their contact details in order to make contact. Staff at our Division for Information Governance would be able to advise further on navigating the conditions of the POPI Act: permission@sun.ac.za.

- **In terms of the steps you follow in the informed consent process, over the telephone,** you will need to **describe in detail in your protocol how the consent process will be documented** (such as recording the date, time, and name of the caller, a note that a prescribed script was used when verbally taking the participant through the consent process, how the process will be witnessed to verify it, and how consent and the witnessing thereof will be documented). Using the original informed consent document that you would have given to a potential participant to read as a guide, you can adapt this into a conversational script that you would follow when making contact with a potential participant.
- In addition to the information about the study, the **informed consent telephonic script** will also need to first establish that you are in fact speaking to the person you intended to contact, and whether they are able to talk to you in a place that is private and where they will not be overheard by others. It should also ensure that **all the necessary elements of informed consent** (e.g. understanding that participation is voluntary, that participants can withdraw at any time with no negative consequences, aspects of confidentiality and any limits to this, who is present during the telephonic informed consent process (e.g. a witness) etc.). This script needs to be submitted as an appendix to the ethics committee.
- **In terms of how you document the consent that participants verbally (telephonically) give**, HREC SoP guidance on documenting informed consent states that "Written informed consent should always be obtained unless an alternative process is adequately justified and approved in advance by HREC" (11.1.5, p. 53).
- **If written consent cannot be obtained**, the non-written consent process must be fully documented and witnessed. NB: See HREC SoPs for the definition of who would qualify as the "**impartial witness**" (i.e. someone independent of the research study) to the consent process: point 22.3.3, page 89.
- See HREC SoP guidance on '**variation on consent procedures'** (11.4, page 55): "HREC may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided HREC finds and documents that…"
- **Explicit guidance on *documenting* informed consent – and exceptions to this**, such as oral, witnessed consent – is outlined in the HREC SoPs section 11.6 pages 60-61. Refer specifically to point 11.6.5, page 61: "Applicants may apply for a waiver of the formal documentation of informed consent. HREC may waive the requirement for the investigator to obtain a signed consent form for some or all participants if…"
- In addition to documenting the informed consent process, you also need to describe in your protocol **how and when you plan to conduct *and record* the telephonic interview,** following similar steps in terms of verifying identity of the participant, as well as **privacy and confidentiality considerations**. **NB: The witness to the informed consent process must *not* be present during the telephonic interview.**
- If you were planning on offering an **incentive or token of appreciation** when interviewing people face to face, you may need to consider alternative options that you can still offer participants and get to them 'virtually'.

Virtual/online audio or video call interviews

- The **same considerations as outlined above** for telephonic interviews apply to interviews that you plan to conduct online or by video call (e.g. Whatsapp, Zoom).
- There are also **additional considerations when using these online/virtual platforms for interviews**.

- You need to describe in your protocol **how you will mitigate risks to privacy and confidentiality on these platforms**, considering potential for breaches of security in electronic forms of communication.
- You will also need to consider the **implications for participants of using these virtual technologies** in terms of, for example, data and connectivity access and costs, and familiarity of your target population with using such technologies. **Remuneration for any costs incurred by participants** is non-negotiable.
- Generally, **simpler is better:** if it is not necessary for the purposes of your research objectives to *see* your participant (i.e. on video calls), would telephonic interviews not be equally appropriate, and more feasible based on the additional 'risks' of online/video calls?

Some things to think about: Consider the impact of COVID on potential participants and participant communities, on their responses, and the data you collect

- Is it ethical to continue with your topic at a time when the world's consciousness is consumed by coronavirus and all its implications?
- Is the research going to place an additional burden on participants during this time of crisis?
- Might the research divert critical personnel / individuals from focusing on responding to the crisis?
- While none of this means that you should not be continuing with your research, it is important that you show that you have thought through these considerations and tried to minimise any potential 'harms' to your participants wherever possible. Some useful guidance documents include:
- The Nuffield Council's short report on **Research in global health emergencies**. Specifically, refer to the section on **the experiences of research participants**. You can also find the full report here.
- The World Health Organization's guidance on **Ethical standards for research during public health emergencies**.
- CIOMS's International Ethical Guidelines for Health-related Research Involving Humans, specifically referring to **Guideline 20 (pages 75-78), "Research in disasters and disease outbreaks".**
- The World Health Organization's Guidelines on managing ethical issues in infectious disease outbreaks, specifically referring to **Chapter 8 (pages 30-34), "Research during infectious disease outbreaks".**

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